

Atopic Dermatitis – Case Study

Recruitment of a global Phase 2a study in moderate to severe Atopic Dermatitis closed 10 weeks ahead of schedule.

Results

- ✓ Patient recruitment closed 10 weeks ahead of projected milestone
- ✓ Screen failure rate of 11% was significantly lower than projected 33%

Sponsor's Feedback

"Great job everyone! This has been a really smooth and well-run study and we really appreciate everyone's hard work to make it happen. It's very exciting to reach this milestone, and we wouldn't be here without you all."

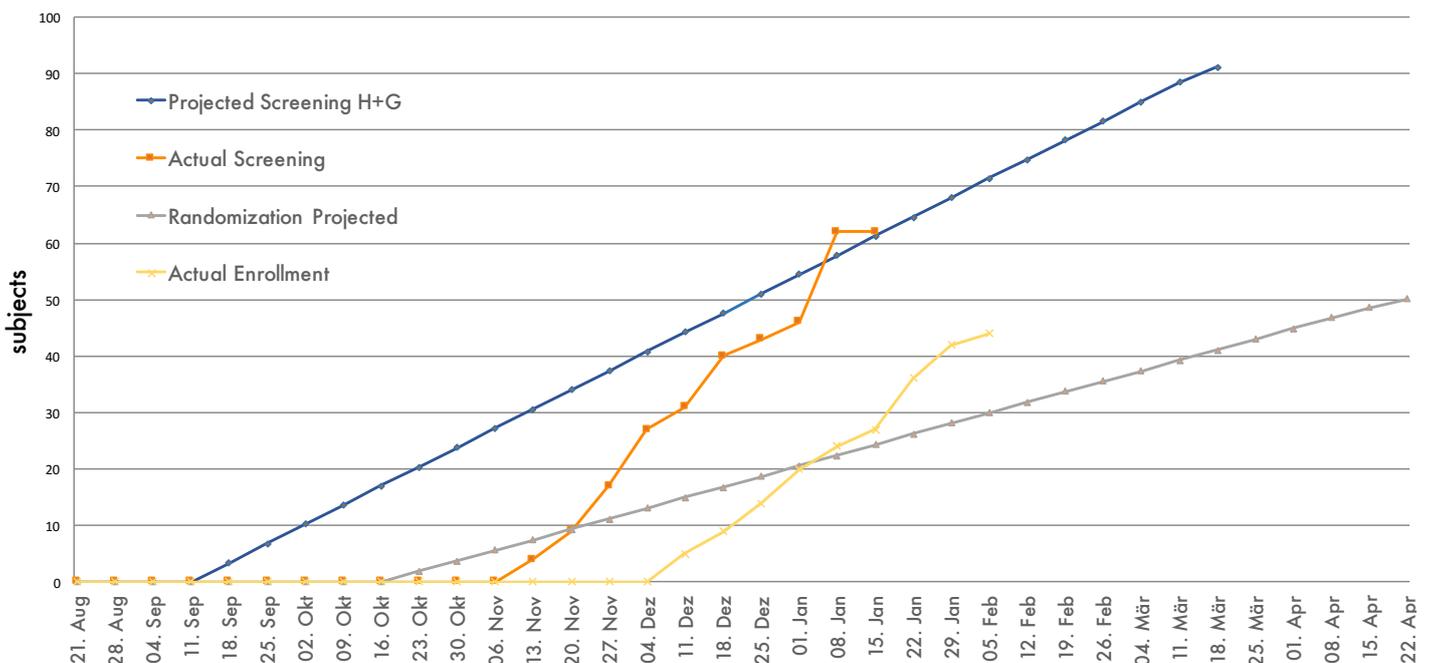
Sponsor Facts

Type of company: public listed company

Headquarters: USA, Maryland und UK, Cambridge

Repeat Customer: yes

Company's focus: auto-immune diseases, oncology, cardiac diseases



We've got Skin in the Game

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Challenges

- 1** High projected screen failure rate and tight inclusion criteria: EASI Score of ≥ 12 at screening and baseline.
- 2** Uncertainty of patients because of therapeutic antibody as new type of IMP.
- 3** Exclusion of typical concomitant medication and long wash-out phase showed high difficulties for the grade of severity.
- 4** Recruitment period ideally is during autumn and winter.

Proinnovera's Measures

- Optimized screening visits by intensive training of Investigators & efficient site selection by detailed feasibility. Lessons Learned from comparable prior studies could be imparted effectively.
- Transparent and professional informed consent conducted by Investigators; established trust by high professionalism of sites
- Investigators explained use of emergency medication in detail to the patients. Thus, emergency medication could be applied in very severe cases to overcome wash-out
- Project planning for study submission and site initiation did consider season specific requirements of indication.

Indication

Atopic dermatitis,
Grade of Severity: moderate to severe

Phase

Ila

Type

Placebo-controlled, randomized, double-blind

Coverage

17 sites in Germany & Hungary

Services

Project Management, Clinical Monitoring,
Regulatory Affairs Management,
Medical Monitoring

Indicators	Projection	Actual
Screen failure rate	33%	11%
Randomized patients	50	51
Recruitment period in weeks	30	24



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Key to Success for your Study

- ✓ Proinnovera’s worldwide partnerships allow for flexible country selection according to indication and study specific requirements.
- ✓ Specialized dermatology CRO: Expertise from more than 100 successfully conducted studies guarantee reliable planning, conduct and control of your international dermatology study.
- ✓ Proinnovera’s value-based company culture continuously shapes our daily work. We believe in a clear and transparent communication structure between all internal and external study team members.

Our primary goal is to deliver fast and efficient solutions for clinical research. We strongly believe that this is the best way to make you successful and to make your product ready for the market.

Our corporate philosophy is based on value-oriented thinking and performance.

At proinnovera, commitment, sustainability and success are the pillars of any cooperation. Giving and keeping our word is our guiding belief and creativity is our contribution!



We are globally dedicated to skin health!



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